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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,486

04/09/2007

Darrell Sleep

P31,747 USA

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FOX ROTHSCHILD LLP
2000 MARKET STREET
10th Floor
PHILADELPHIA, PA 19103

EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,486	Applicant(s) SLEEP ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2006 and 20 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claim 42 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 8-10 and 17-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a “2 μ m-family plasmid”. This represents a genus of plasmids. At page 1 of the specification, first full paragraph, Applicants disclose:

“As a family of plasmids these molecules share a series of common features in that they possess two inverted repeats on opposite sides of the plasmid, have a similar size around 6-kbp (range 4757 to 6615-bp), at least three open reading frames, one of which encodes for a site specific recombinase (such as FLP in 2 μ m) and an autonomously replicating sequence (ARS), also known as an origin of replication (ori), located close to the end of one of the inverted repeats...Despite their lack of discernible DNA sequence homology, their shared molecular

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architecture and the conservation of function of the open reading frames have demonstrated a common link between the family members.”

Thus, while 2 μ m-family plasmids have several common features, i.e., two inverted repeats, a certain size range, 3 or more open reading frames, one of which is for a recombinase and an ARS origin of replication. However, of these features, the size range and the presence of an ARS are not unique to any of the thus far identified 2 μ m plasmids, and thus do not serve to describe them in a manner which allows them to be distinguished from other plasmids. Also, the presence of three or more open reading frames is not unique to the 2 μ m plasmids thus far identified. As such, the presence of a recombinase and a pair of inverted repeats distinguishes 2 μ m plasmids over the many other types of plasmids in the art. Structurally, inverted repeats could be of any sequence so long as they are repeats. Thus, there is a substantial amount of variation possible with respect to this feature of the invention. A recombinase, and therefore a gene encoding a recombinase, is defined functionally, i.e., there is no significant structure which draws together all recombinases. The genus of all recombinases is therefore very large, i.e., there is a substantial amount of variation among recombinases, and therefore recombinase genes. Finally, Applicants state at page 1, lines 25 and 26, that there is no “discernible DNA sequence homology” between the plasmids, indicating that only the recited structural features draw together the genus. The 2 μ m plasmids cited in the specification come from only four biological genera of yeast, and thus represent only a small portion of the potential genus of plasmids possessing the features discussed above, i.e., they do not constitute a representative sample of 2 μ m plasmids. One of skill in the art would not have recognized, therefore, that Applicants were

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in possession of the full scope of the claimed invention, and as such, the instant claims do not meet the written description requirement of 35 USC § 112, first paragraph.

Claims 7, 12 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a “variant” of a DNA or protein sequence. However, given the open-ended nature of “variant”, essentially any sequences potentially would be encompassed. Thus, there would be a substantial amount of variation within the genus. No examples of actual variants of the recited DNAs or proteins have been set forth in the specification, and as such, a representative sample of the encompassed embodiments has not been disclosed. The variants of DNA sequences would lead to variants in the proteins sequences thus encoded, and alterations in protein structure can lead to alterations in function of said protein. No relationship between the structure of a protein and its function has been set forth by the instant specification, and the level of knowledge of the relationship between structure and function for proteins was not sufficient in the art at the time of filing for one of skill to have known a priori what variation would lead to what function in said protein. As such, one of skill would not have recognized that Applicants were in possession of the full scope of the invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims all recite a “2µm-family plasmid”. However, it is not clear which definition in the specification applies. For example, the definition of a member of this family at page 1 has a different size range for the plasmids than the definition at page 7, near the top. As such, the metes and bounds of the claims are unclear.

Claims 2, 4, 10 and 16 recite the phrase “derived from”, as well as “derived” at the end of claim 4. However, this term encompasses changes of an unspecified nature to the starting material, and thus fails to limit the resulting “derived” material, as any number and type of transformative steps might be involved. As such, the metes and bounds of the claims are rendered unclear.

Claim 3 recites “the naturally occurring 2µm-family plasmid”. However, this phrase lacks a proper antecedent basis in Claim 1.

Claims 7, 12 and 23-27 recite a “variant” of a DNA or a protein sequence. However, this term is unqualified or unlimited, and thus would encompass any DNA or protein, as any one starting molecule could be transformed to any other by some series of unspecified steps. As such, it is not clear what molecules are encompassed as “variants”, rendering the metes and bounds of the claims unclear.

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Regarding claims 9 and 23, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 10, 16 and 33, the phrase “preferably” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 18, 33 and 34 recite: “a position as defined in any one of the preceding claims”; “a position as defined by any one of claims 1 to 16”; or “at a position as defined in claim 1”. However, in each instance, it is not clear which positions in the preceding claim(s) were intended. For example, would the FLP or REP2 gene of claim 1 be such a position? They are positions defined in claim 1, and it is not clear from the instant claims that they would be excluded by this limitation.

Claim 39 recites “based on” several times. However, it is not clear what this term means, e.g., it is not clear exactly which portions of the plasmids are present, and in what orientations, numbers, and what other sequences have been included.

Claim 40 recites “substantially 100%”. However, it is not apparent how this differs from “100%” or “99.9%” which preceded it in the claim. This term is not defined in the specification, nor is it a recognized term of art with a precise definition.

Claim 44 recites “a commercially acceptable level of purity.” However, this term is not precisely defined in either the specification or the art, and would be presumed to vary from protein to protein, and from (commercial) use to use.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
27 April 2009

/James S. Ketter/
Primary Examiner, Art Unit 1636